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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,303	04/14/2000	Brian Haab	S99-066	9147

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/550,303	HAAB ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,13-16,18,31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,13-16,18,31 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-DD

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 February 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 25 February 2005 in which claims 31 and 36 were amended and claims 1-7, 9 and 38-40 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 13 August 2003 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new ground for rejection. New grounds for rejection are discussed.

Claims 10, 13-16, 18, 31 and 33-37 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 31 and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 31, Winkler et al disclose an array of discrete polypeptides, each of which is at least 50 amino acids in length wherein the array comprises 1000 or more discrete regions of distinct polypeptides/cm^2 (Column 17, lines 49-58) and wherein the support is a slide (Column 4, lines 23-25).

Regarding Claim 33-35, Winkler et al disclose the array wherein the polypeptides are immunological receptors e.g. antibodies or antigens (Column 6, lines 8-18).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 10, 13-16, 18, 31 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (GB 2099578, published 8 December 1982) and Chang (U.S. Patent No. 4,829,010, issued 9 May 1989).

Regarding Claim 31, Gordon et al disclose an array of discrete polypeptides, each of which is at least 50 amino acids in length (antibodies or antigen, Abstract) and wherein the array comprises 1000 or more discrete regions of distinct polypeptides/cm^2 (i.e. 10^5 individual tests/10 cm^2 page 11, lines 13-14) wherein their arrays of at least 1000 antibodies or antigens enables detection of an "unlimited number of antibody-antigen reactions simultaneously", Abstract). Gordon further teaches the support is of any suitable shape e.g. films, sheets, or plates and bonded to any inert carrier e.g. glass or plastic film (page 3, lines 62-65), which clearly suggests the support is a slide, but they do not specifically teach the term "slide".

Chang discloses a similar array of discrete polypeptides, each of which is at least 50 amino acids in length (antibodies, Abstract) and wherein the array comprises at least100 discrete regions of distinct polypeptides/cm^2 (Column 4, lines 22-34) wherein the preferred support is a slide (Column 2, lines 7-10). Chang further teaches the slide is preferred because it is light transparent (Column 2, lines 7-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to increase the at least 100 regions of Chang to at least 1000 as taught by Gordon et al. One of ordinary skill in the art would have been motivated to do so based on Gordon et al wherein it is taught that their arrays of at least 1000 antibodies or antigens enables detection of an "unlimited number of antibody-antigen reactions simultaneously", Abstract).

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the slide of Chang to the broadly defined substrate of Gordon et al to thereby provide a light-transparent support as taught by Chang (Column 2, lines 7-8) for the obvious benefit of permitting detection and analysis of reactions on the support.

Regarding Claims 33-34, Gordon et al teach the polypeptides are immunological receptors i.e. antibodies (Abstract) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 35, Gordon et al teach the polypeptides are antigens (Abstract).

Regarding Claim 36, Gordon et al teach the support is film-coated glass wherein the coating is selected from a range of materials including those having cationic properties e.g. polyesters and polyamindes (page 3, lines 48-54).

Regarding Claim 37, Gordon et al teach their arrayed polypeptides are used to detect antibody-antigen reactions (Abstract), hence the antibodies maintain their native structure. Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

7. Claims 10, 13-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (GB 2099578, published 8 December 1982) and Chang (U.S. Patent No. 4,829,010, issued 9 May 1989) as applied to Claim 31 above and further in view of Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996).

Regarding Claim 10, Gordon et al and Chang teach the array of Claim 31 as discussed above wherein the array comprises 1000 or more discrete regions of distinct polypeptides/cm^2 (Gordon: page 11, lines 13-14 and page 3, lines 62-65, Chang: Column 2, lines 7-10 and Column 4, lines 22-34). Gordon teaches the array is produced using Hamilton microspotters (page 6, lines 61-63) but they do not teach a spotting volume of 0.002 to 2nl. However, Beattie teaches a similar array of more than 1000 or more discrete regions/cm^2 wherein the preferred Hamilton spotter dispenses 1nl volumes (Column 14, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the spotter of Beattie to produce the arrays of Gordon and Chang. One of ordinary skill

in the art would have been motivated to do so based on the desired use for closely spaced spotting as taught by Beattie (Column 14, lines 16-28).

Regarding Claims 13-14, Gordon et al teach the polypeptides are immunological receptors i.e. antibodies (Abstract) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 15, Gordon et al teach the polypeptides are antigens (Abstract).

Regarding Claim 16, Gordon et al teach the support is film-coated glass wherein the coating is selected from a range of materials including those having cationic properties e.g. polyesters and polyamindes (page 3, lines 48-54).

Regarding Claim 18, Gordon et al teach their arrayed polypeptides are used to detect antibody-antigen reactions (Abstract), hence the antibodies maintain their native structure. Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

8. Claims 10, 13-15, 18, 31, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) in view of Chang (U.S. Patent No. 4,829,010, filed May 9 1089).

Regarding Claim 31, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a planar solid support wherein the microarray comprises 1000 or more discrete regions/cm^2 (Fig. 1, Column 5, line 66-Column 6, line 6 and Claims 1 and 15) they teach binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Zubay defines antibodies as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). Beattie further teaches the support is a slide (Column 11, lines 40-42) but they do not specifically teach polypeptides arrayed on a slide.

Chang teaches a similar array of discrete polypeptides, each of which is at least 50 amino acids in length (antibodies, Abstract) and wherein the array comprises at least100 discrete regions of distinct polypeptides/cm^2 (Column 4, lines 22-34) wherein the preferred support is a slide (Column 2, lines 7-10). Chang further teaches the slide is preferred because it is light transparent (Column 2, lines 7-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the slide of Chang to the broadly defined substrate of Gordon et al to thereby provide a light-transparent support as taught by Chang (Column 2, lines 7-8) for the obvious benefit of permitting detection and analysis of reactions on the support.

Regarding Claim 33-34, Beattie teaches the microarray wherein the binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 35, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 37, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions.

Furthermore, Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

Regarding Claim 10, Beattie and Chang teach a microarray of discrete polypeptides on a planar solid support of Claim 31 as discussed above and Beattie teaches the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52).

The preceding rejection is based on judicial precedent following In re Best (195 USPQ 430) and In re Fitzgerald, 205 USPQ 594 because Beattie and Chang are silent with regard loading a polypeptide solution into an elongate capillary channel and tapping its tip onto the support to dispense the solution.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Furthermore, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

> is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, because Beattie and Chang teach the microarray as claimed, the claimed process of making the microarray does not distinguish over the teaching of prior art.

Regarding Claim 13-14, Beattie teaches the microarray wherein the binding reagents includes antibody-antigen binding (Column 7, lines 20-21) (Column 15) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 15, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 18, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions. Furthermore, Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

9. Claim 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) in view of Chang (U.S. Patent No. 4,829,010, issued 9 May 1989) as applied to Claim 10 above and further in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claims 16 and 36, Beattie and Chang teach the microarray comprising binding reagents deposited at defined positions on a planar solid support (Claims 1 and 15) and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52) but they do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Beattie and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 9, 2005